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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,662	12/28/2001	John M. Stewart	4726-1-CON	4618

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,662	STEWART ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-84* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In the preliminary amendment filed December 28, 2001, claims 1-15 have been cancelled, and new claims 16-84 have been added. Thus, claims 16-84 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U. S. C. 121:

(1). Claims 16, 19 and 22, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound is an amino acid derivative, classified in class 562, subclass 433.

(2). Claims 17, 18, 20, 21, 23 and 24, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound is an amino acid derivative, classified in class 562, subclass 433 and class 424, subclass 9.1.

(3). Claims 25, 28 and 31, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound is a dipeptide derivative, classified in class 514, subclass 19.

(4). Claims 26, 27, 29, 30, 32 and 33, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound is a dipeptide derivative, classified in class 514, subclass 19, and class 424, subclass 9.1.

(5). Claim 34, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound is a tripeptide, classified in class 514, subclass 18.

(6). Claims 35 and 36, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound is a tripeptide, classified in class 514, subclass 18, and class 424, subclass 9.1.

(7). Claim 37, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound is a peptide having 4-6 amino acid residues, classified in class 514, subclass 17.

(8). Claims 38 and 39, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound is a peptide having 4-6 amino acid residues, classified in class 514, subclass 17, and class 424, subclass 9.1.

(9) Claim 40, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound is a cyclic peptide, classified in class 514, subclass 9.

(10). Claims 41 and 42, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound is a cyclic peptide, classified in class 514, subclass 9, and class 424, subclass 9.1.

(11). Claims 43 and 46, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound contains a linking group which links two monomers selected from an amino acid derivative, a dipeptide and a tripeptide, classified in class 514, subclass 2.

(12). Claims 44, 45, 47 and 48, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound contains a linking group which links two monomers selected from an amino acid derivative, a dipeptide and a tripeptide, classified in class 514, subclass 2, and class 424, subclass 9.1.

(13). Claim 49, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound contains a linking group which links two monomers selected from a tetrapeptide, a pentapeptide and a hexapeptide, classified in class 514, subclass 2.

(14). Claims 50 and 51, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound contains a linking group which links two monomers selected from a tetrapeptide, a pentapeptide and a hexapeptide, classified in class 514, subclass 2, and class 424, subclass 9.1.

(15). Claim 52, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound contains a linking group which links two monomers selected from a peptide having 7 to 10 amino acid residues, classified in class 514, subclass 2.

(16). Claims 53 and 54, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound contains a linking group which links two monomers selected from a peptide having 7 to 10 amino acid residues, classified in class 514, subclass 2, and class 424, subclass 9.1.

(17). Claim 55, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound is a polypeptide, classified in class 514, subclass 2.

(18). Claims 56 and 57, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound is a polypeptide, classified in class 514, subclass 2, and class 424, subclass 9.1.

(19). Claim 58, drawn to a compound or a pharmaceutically acceptable salt thereof, where the compound contains a linking group which links two monomers of a polypeptide, classified in class 514, subclass 2.

(20). Claims 59 and 60, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound contains a linking group which links two monomers of a polypeptide, classified in class 514, subclass 2, and class 424, subclass 9.1.

(21). Claims 61-84, drawn to a method of inhibiting tumor growth in an animal or inducing apoptosis of cancer cells comprising administering a compound or a pharmaceutically acceptable salt thereof, where the compound is a polypeptide, classified in class 514, subclass 2, and class 424, subclass 9.1.

Should Group 1-19 or 20 be elected, applicant is required to elect one (1) amino acid derivative or one (1) peptide with a defined sequence or structure. Each amino acid derivative or peptide, which contains a different sequence, has different chemical and physical properties and produces a different effect in the treatment (see activities in

Tables 1-3 for various compounds), is considered patentably distinct. This is not species election. If there is a core sequence or structure in the elected compound, applicants should point out the core sequence or structure, and the sequences or structures related to this core structure for examination. All other amino acid derivatives and peptides encompassed by the claims will be withdrawn by the Examiner as being drawn to non-elected invention.

2. The inventions are distinct, each from the other because of the following reasons:

The products of Inventions 1, 3, 5, 7, 9, 11, 13, 15 17 and 19 are distinct from each other because they are physically and chemically distinct entities and produce different effects in the treatment (see activities in Tables 1-3 for various compounds).

The methods of Inventions 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 and 21 are distinct from each other because different compounds are administered to the animal and different effects are produced in the treatment (see activities in Tables 1-3 for various compounds).

The product of Invention 1 and the method of Invention 2 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention 3 5, 7, 9, 11, 13, 15 17, 19 or 21 can be used in the method of Invention 2. The same relationship between the product and the process of use is also applied to Inventions 3 and 4, 5 and 6, 7 and 8, 9 and 10, 11 and 12, 13 and 14, 15 and 16, 17 and 18, 19 and 20.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by different classification and the recognized divergent subject matter, and because Inventions of 1-21 require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Robert Traver on June 7, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

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June 7, 2004